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APPLICATION NO. 20,	FILING DATE 4/12/95	OUTER FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
			M 4544-011-25-

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33M1/0205

EXAMINER
NASSER, R

ART UNIT	PAPER NUMBER
3311	

DATE MAILED: 02/05/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	480503	Applicant(s)	Quinn et al
Examiner	Nassar	Group Art Unit	3311

Responsive to communication(s) filed on 12/16/97.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 45-63 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 45-63 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The examiner notes that the following grounds of rejection is newly applied to claims 46-52. Accordingly, the finality of the prior office action is being withdrawn and the following action issued.

The examiner acknowledges applicant's request under 37 C.F.R. § 1.607 to provoke an interference with U.S. patent number 5,435,308 to Gallup et al. However, as none of the present claims are allowable, the interference is not being set up.

The drawings are objected to under 37 C.F.R. § 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the fiber optic filaments inside the lumen and the fiber optic coupler associated with the catheter must be shown or the feature cancelled from the claim. No new matter should be entered.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l). Correction of the following is required: Applicant does not have corresponding terminology in the specification to the fiber optic coupler and the filaments, as required by the rule.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains,

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or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, fails to provide support for the invention, as is now claimed. Claims 62 and 63 recite that the lumen dedicated to measuring distal catheter pressure includes surfaces defining a port and that the port is for measuring distal catheter pressure. Applicant points to page 16, lines 35-37 and page 24, line 32, as providing support for these features. However, upon review of this sections of the disclosure, no mention of a port in connection to the pressure measuring lumen for measuring distal catheter pressure is made. Accordingly, claims 62 and 63 introduce new matter. Clarification is required.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling description of the claimed invention. Claims 45, and 57-60 recite a port to enable injection of a fluid into the bloodstream. While there is basis for the injectate port, it is unclear from the specification what the purpose of injecting fluid is, as the principle of operation of the device is to add heat, not a cold bolus, for measuring cardiac output. Applicant should clarify the purpose of the fluid injection.

Clarification is required.

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Claims 45, 53-63 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 45-54 and 56-63 are rejected under 35 U.S.C. § 103 as being unpatentable over Willis et al in view of Khalil '910.

Willis et al shows all of the features of the claims except that it measures cardiac output using a cold bolus injection. Khalil teaches that cold bolus injections and using external heaters heat the blood are equivalent methods of measuring cardiac output (see background section). Accordingly, it would have been obvious to modify Willis et al to use a heating coil, rather than a cold bolus injection, as it is merely the substitution of one

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known equivalent measurement technique for another. Claim 46 is rejected in that in addition the features of the invention discussed above, Willis et al shows the port P' on a "necked down" portion of the catheter. Claim 47 is rejected in that the necked down portion includes a portion of the catheter that is 14-15 centimeters from the distal end of the device. Claim 48 is rejected in that the heater is a coil wrapped about the necked down portion. Claim 49 is rejected in that there is a thermistor distal to the heater in the combination. Claims 50-52 are rejected in that the coil of the combination has center to center spacings such that adjacent turns do not contact each other, has an outer sheath and the diameter of the coil approximates that of the catheter when wrapped about the catheter. Claim 53 is rejected in that the port P/M' is distal to the interface. Claim 54 is rejected in that the exact distance between the end of the catheter and the heater varies with catheter size and would have been obvious to one skilled in the art. Claims 56-58 and 61-63 are rejected in that the combination shows all of the features of the claims. Claim 59 and 60 are rejected in that there is a fluid injectate lumen and port P/M' for injecting a fluid into the blood, that is distal to the interface.

Claim 55 is rejected under 35 U.S.C. § 103 as being unpatentable over Willis et al in view of Khalil as applied to claims 45-54, 56-58, and 61-63 above, and further in view of

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Grise. Grise teaches that a substrate based heater is an improvement over a single wire of Khalil, in that the cost is much less and the heaters are more flexible in use.

Accordingly, it would have been obvious to modify the above combination to use the substrate based heater of Grise, for the reasons given above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Nasser whose telephone number is (703) 308-3251 or to Angela Sykes, the Supervisory Patent Examiner for Art Unit 3311, at (703) 308-2713.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858. In addition, the Group Fax number is (703) 305-3590.

Robert S. Nasser

RLN
February 4, 1997

ROBERT NASSER
PATENT EXAMINER
GROUP 2000